

REMARKS

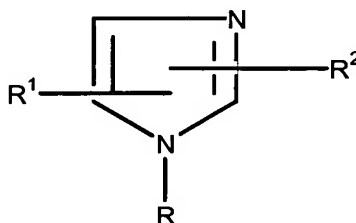
Claims 1, 8, 15, 20-23 and 33-35 have been amended in this Amendment B After Final to correct obvious typographical errors. No new matter has been added by the claim amendments. No new amendments to the specification have been made in this Amendment B After Final. After entry of this Amendment B After Final, claims 1-9 and 11-42 will be pending.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of Claims 1-9, 11-13, 20-26 and 27-33, 36-39 and 42 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-9, 11-13, 20-26 and 27-33, 36-39 and 42 under 35 U.S.C. §103(a) as being unpatentable over Scholz (US 4,378,972) (Scholz I) in view of Scholz (US 5,139,955) (Scholz II).

Independent claim 1 is directed to a one component Karl Fischer reagent comprising iodine and a base comprising imidazole and a substituted imidazole. The substituted imidazole has the general formula:



wherein R and R¹ are independently selected from the group consisting of hydrogen, phenyl, and a monovalent substituted or unsubstituted saturated or unsaturated hydrocarbyl moiety having from 1 to about 4 carbon atoms which may or may not be interrupted with hetero atoms, and R² is phenyl, a fused benzo ring, or a monovalent substituted or unsubstituted saturated or unsaturated hydrocarbyl moiety having from 1 to about 4 carbon atoms which may or may not be interrupted with hetero atoms. The molar ratio of imidazole to substituted imidazole in claim 1 is from about 0.3:2 to

about 2:0.3. The reagent in claim 1 is suitable for use as a one component reagent in volumetric Karl Fischer titrations.

Independent claim 42 is directed to a one component Karl Fischer reagent comprising iodine and a base comprising imidazole and a substituted imidazole. The substituted imidazole is selected from the group consisting of 1-methylimidazole, 1-ethylimidazole, 1-propylimidazole, and 1-butylimidazole. The molar ratio of imidazole to substituted imidazole is from about 0.3:2 to about 2:0.3. The reagent in claim 42 is suitable for use as a one component reagent in volumetric Karl Fischer titrations.

Scholz I discloses Karl Fischer titration reagents containing an amine, sulfur dioxide, and iodine. The amine is an aliphatic amine optionally containing 1, 2, or 3 oxygen atoms, the molar ratio of amine to sulfur dioxide being from 0.5:1 to 1.3:1; or, the amine is a five- or six-membered, optionally substituted, heterocyclic compound having at least 2 hetero-atoms, one hetero-atom at least being a nitrogen atom. Suitable heterocyclic compounds disclosed by Scholz I include imidazole and a number of substituted imidazoles. As specifically noted by the Office, Scholz I does not teach using a mixture of an imidazole and a substituted imidazole. The use of imidazole in combination with a substituted imidazole is a requirement of claims 1 and 42. Additionally, Scholz I fails to disclose any required ratio of these components as required by claims 1 and 42. In an effort to remedy the admitted shortcomings of Scholz I, the Office cites for combination therewith Scholz II.

As noted in applicants' Amendment A, Scholz II discloses Karl Fischer reagents solely for use in coulometric Karl Fischer titrations. The reagents disclosed in Scholz II comprise an alcoholic solvent with a reactive base mixed with sulfur dioxide and an iodide conducting salt. The reactive base may contain imidazole and/or imidazole derivatives and/or diethanolamine and/or triethanolamine. As noted in the reference, each reagent contains an iodide or a mixture of different iodides (see Col. 3, lines 55-56). Scholz II fails to disclose any teaching, suggestion, or examples related to the ratio of amounts of imidazole to imidazole derivative suitable for use in the coulometric reagents. Additionally, and importantly, none of the seven Examples set forth in Scholz II disclose the combination of an imidazole and an imidazole derivative in any

amount. Additionally, Scholz II fails to teach or suggest (1) a reagent suitable for use in a one component Karl Fischer volumetric titration and (2) a reagent comprising iodine.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. Section 2143 requires that the Office must demonstrate that (1) the prior art references teach or suggest all of the claim limitations; (2) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings, and (3) there is some reasonable expectation of success. As noted in M.P.E.P. Section 2142:

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done.¹ When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper.²

Moreover, as noted in M.P.E.P. Section 2143.01, "[t]he mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."³

The Office has not, and cannot meet its burden under number (1) and number (2) above, as Scholz I in combination with Scholz II does not teach or suggest all claimed elements of the applicants' claimed invention, nor would one skilled in the art have been motivated to modify Scholz I in combination with Scholz II to arrive at each and every claimed element of the applicants' claimed invention.

As noted above, a combination of Scholz I and Scholz II fails to meet the requirements of M.P.E.P. Section 2143. First, the combination fails to teach or suggest each and every element of the claims. Claim 1 requires that the ratio of imidazole to

¹ "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985) (emphasis added).

² citing *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986).

³ citing *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990).

substituted imidazole be from about 0.3:2 to about 2:0.3. Neither of the cited references alone, or in combination, teaches nor suggests this claim requirement. Clearly, Scholz I cannot teach or suggest this requirement as it fails to teach or suggest the use of an imidazole in combination with a substituted imidazole. Scholz II does suggest that an imidazole can be used in combination with a substituted imidazole, but does not teach or suggest any amounts or ratios of one component to the other. Claim 1 clearly requires a set ratio of imidazole to substituted imidazole; neither of the references alone or in combination teach or suggest this required ratio. As such, claim 1 cannot be said to be obvious in view of either reference alone, or in combination.

Applicants note that, regarding the ratio requirement of claim 1, the Office states on page three of the Final Office action that it would have been obvious for anyone of ordinary skill in the art to optimize these ratios to obtain the best results for the reagent. Because neither cited reference provides any guidance or suggestion of the ratios of imidazole to substituted imidazole, it is unclear what the Office is referring to when it cites "these ratios." There are simply no ratios set forth in either cited reference to optimize. As such, the optimization of a non-existent ratio does not make any sense; that is, even though Scholz II does suggest the use of an imidazole in combination with a substituted imidazole (in a coulometric system) it would not be obvious to one skilled in the art to optimize that amount of each component relative to the other when no guidance is given. How could one skilled in the art know when optimization was obtained? Again, because both cited references alone, or in combination, fail to disclose or suggest each and every element of claim 1, the Office has failed to make a *prima facie* case of obviousness and claim 1 cannot be said to be obvious in view of them.

Notwithstanding the fact that the cited references fail to disclose each and every element of claim 1 as discussed above, there is simply no motivation in the references themselves, or available to one skilled in the art at the time of the invention, to combine these references and arrive at applicants' claim 1 (without using impermissible hindsight which, with all due respect, it appears that the Office has done in this case). It is clear that neither of the references themselves provide any suggestion or motivation to make the combination suggested by the Office. Scholz I is specifically directed to one

component volumetric Karl Fischer titrations while Scholz II is specifically directed to one component coulometric titrations; neither reference provides any motivation to look to the other to provide any components or advantages. Apparently recognizing that the cited references themselves fail to provide the required suggestion or motivation to combine, the Office states that it would have been obvious to one skilled in the art to slightly modify the Karl Fischer reagent of Scholz I by using a mixture of imidazole and its derivative, as indicated in Scholz II, **because it gives more flexibility in adjusting the composition of the reagent.** Applicants are unsure what "more flexibility"⁴ means and how the combination of references provides this. Without any suggestion of a shortcoming in the one component volumetric reagents of Scholz I in either of the cited references, why would one skilled in the art be motivated to add additional components to the reagent of Scholz I (i.e., a substituted imidazole) and thereby increase costs and increase the complexity of making the reagent? It would appear that due to the additional cost and burden of making the reagent the requirement of additional components in the reagent of Scholz I would actually provide **less** flexibility. There is clearly no teaching or suggestion in either reference that a combination of imidazole and substituted imidazole provides any benefit; let alone any benefit in a one component Karl Fischer reagent as claimed in claim 1.

In contrast, applicants disclose throughout their specification that imidazole, when used without a substituted imidazole in a one component volumetric Karl Fischer reagent, is subject to forming undesirable precipitations or crystals of imidazolium sulfate, which can lead to problems in the flexible tube systems of the Karl Fischer apparatus. Neither cited reference notes this problem. Without noting a problem such as this with the use of imidazole alone in a one component Karl Fischer volumetric

⁴ Applicants note, as mentioned above, that it is incumbent upon the Office to present **a convincing line of reasoning** as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Applicants respectfully submit that such a convincing line of reasoning has not been set forth by the Office; simply stating that by combining the teachings more flexibility in adjusting the composition is achieved does not provide a convincing line of reasoning as to why the references would have been combined. Applicants also submit that such a convincing line cannot be set forth, as the references and knowledge available to one skilled in the art at the time of the invention cannot provide the required motivation.

reagent, there is simply no motivation to combine the cited references. As such, claim 1 cannot be said to be obvious in view of these references.

Based on the foregoing, independent claim 1 is patentable over Scholz I in view of Scholz II. Claims 2-9, 11-13, 20-26 and 27-33 depend directly or indirectly from independent claim 1. As such, claims 2-9, 11-13, 20-26 and 27-33 are patentable for the same reasons set forth above, as well as for the additional elements they require. Independent claim 42 is similar to claim 1 and is patentable for the same reasons set forth above, as well as for the additional elements it requires.

2. Rejection of Claims 14-19, 21 and 40 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 14-19, 21 and 40 under 35 U.S.C. §103(a) as being unpatentable over Scholz I in view of Scholz II, as applied to claims 1-9, 11-13 and 27-33, 36-39 and 42, and further in view of Fischer et al. (US 4,851,352) (Fischer).

Claims 14-19 and 21 depend directly or indirectly from independent claim 1 and are patentable for the same reasons discussed above, as well as for the additional elements they require. Notwithstanding the foregoing, Scholz I in view of Scholz II and further in view of Fischer fails to teach or suggest each and every claimed element of the applicants' dependent claims 14-19 and 21.

The applicants' dependent claims 14-19 and 21 include an alcohol solvent as an additional element in the Karl Fischer reagent set forth in independent claim 1. Specifically, the alcohol solvent is an ethylene glycol monoalkylether (claims 14-17), propylene glycol monoalkylether (claims 18-19) or diethylene glycol monoethyl ether (claim 21).

Independent claim 40 is similar to independent claim 1, and is directed to a one component Karl Fischer reagent comprising iodine and from about 0.8 moles/Liter to about 1.3 moles/Liters imidazole, from about 0.6 moles/Liter to about 1 mole/Liter 2-methylimidazole, from about 0.1 moles/Liter to about 0.5 moles/Liter Imidazole hydroiodide, from about 0.75 moles/Liter to about 1.6 moles/Liter sulfur dioxide, and from about 780 grams/Liter to about 820 grams/Liter diethylene glycol monoethylether.

The reagent in claim 40 is suitable for use as a one component reagent in volumetric Karl Fischer titrations.

As discussed above, Scholz I in view of Scholz II fails to teach or suggest each and every claimed element of the claims, nor is there any motivation in the references themselves, or available to one skilled in the art, to modify Scholz I in combination with Scholz II to arrive at the applicants' claim 1. As noted by the Office, Scholz I in view of Scholz II does not teach or suggest using the alcohol solvent(s) claimed by the applicants in dependent claims 14-19 and 21 and independent claim 40. In an effort to remedy the admitted shortcomings of Scholz I in view of Scholz II, the Office cites for combination therewith, Fischer.

Fischer discloses a solvent composition for use in a reagent for the determination of water by the Karl Fischer method. The solvent requires the combination of (1) an ethylene glycol monoalkyl ether and (2) a tetraalkylated ammonium salt as a Karl Fischer solvent, the combination asserted as being an improvement over ethylene glycol monoalkyl ether alone. Specifically, Fischer states in Col. 1, lines 59-63 that Pittsburg Conference Abstracts No. 1156, (1985) discloses that ethylene glycol monomethyl ether is unsuitable for the determination of water in aldehydes and ketones because of the formation of acetals and ketals, respectively. Furthermore, Fischer states in Col. 2, lines 4-10 that his solvent composition comprising a combination of ethylene glycol monoalkyl ethers and tetraalkylated ammonium salts is particularly suitable for the problematic determination of the amount of water in aldehydes and ketones. As such, Fischer clearly acknowledges that ethylene glycol monoalkyl ether alone is unsuitable for the determination of water in some circumstances.⁵

Accordingly, Fischer does not teach or suggest the use of ethylene glycol monoalkylethers, propylene glycol monoalkylethers, and diethylene glycol monoalkylethers alone as an alcohol solvent for use in a one component Karl Fischer reagent comprising iodine and a base comprising imidazole and a substituted imidazole,

⁵ This fact is underscored by the specific requirement of this combination in claim 1 which states, in relevant part, "...the improvement wherein said solvent is a solvent composition consisting essentially of a monoalkyl ether of an ethylene glycol and a tetraalkylated ammonium salt which together are effective for use as a Karl Fischer solvent."

wherein the reagent is suitable for use as a one component reagent in volumetric Karl Fischer titrations. Rather, Fischer discloses the combination of ethylene glycol monoalkylethers with tetraalkylated ammonium salts in a solvent composition for use in a Karl Fisher reagent. Additionally, and significantly, Fischer not only does not teach or suggest the use of an alcohol solvent alone in a one component Karl Fischer reagent, Fischer appears to be teaching away from the use of such alcohol solvents alone, by combining them with tetraalkylated ammonium salts to overcome deficiencies disclosed in the prior art. The applicants' dependent claims 14-19 and 21 and independent claim 40 do not require the use of an alcohol solvent in combination with a tetraalkylated ammonium salt in a one component Karl Fischer reagent comprising iodine and a base comprising imidazole and a substituted imidazole. Notably, tetraalkylated ammonium salts are not mentioned at any point in the applicants' specification.

Based on the foregoing, dependent claims 14-19 and 21 and independent claim 40 are patentable over Scholz I in view of Scholz II, as applied to claims 1-9, 11-13 and 27-33, 36-39 and 42, and further in view of Fischer.

3. Rejection of Claims 34 and 35 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 34 and 35 under 35 U.S.C. §103(a) as being unpatentable over Scholz I in view of Scholz II, as applied to claims 1-9, 11-13, 20-26 and 27-33, 36-39 and 42, and further in view of Sherman et al. (Accreditation and Quality Assurance, May 1999).

Claims 34 and 35 depend indirectly from independent claim 1 and are patentable for the same reasons discussed above, as well as for the additional elements they require. Notwithstanding the foregoing, Scholz I in view of Scholz II and further in view of Sherman et al. fails to teach or suggest each and every claimed element of the applicants' dependent claims 34 and 35.

The applicants' dependent claims 34 and 35 include a pH range of from about 5.5 to about 8 as an additional element in a one component Karl Fischer reagent comprising iodine, a base comprising imidazole and a substituted imidazole, wherein the molar ratio of imidazole to substituted imidazole is from about 0.3:2 to about 2:0.3,

and wherein the reagent is suitable for use as a one component reagent in volumetric Karl Fischer titrations.

As discussed above, Scholz I in view of Scholz II fails to teach or suggest each and every claimed element of the claims, nor is there any motivation in the references themselves, or available to one skilled in the art, to modify Scholz I in combination with Scholz II to arrive at the applicants' claim 1. As noted by the Office, Scholz I in view of Scholz II does not specifically indicate an optimal pH range for his Karl Fischer reagent. In an effort to remedy the admitted shortcomings of Scholz I in view of Scholz II, the Office cites for combination therewith, Sherman et al.

Sherman et al. discloses a Karl Fischer reagent comprising imidazole, sulfur dioxide, iodine, and potassium iodide in N-methylformamide. As the Office notes, a Google search indicates that Sherman et al. mentions in passing that the pH of the Karl Fischer reagent may be, *i.e.*, 5.5 to 8. Indeed, it is established in the art that this pH range is the optimal range, since in the pH range of 5.5 to 8 all of the sulfur dioxide is available as methyl sulfite; therefore the maximum reaction rate may be achieved.

However, even when combined, Scholz I in view of Scholz II and further in view of Sherman et al. fails to teach or suggest each and every claimed requirement of the applicants' claims, as these references do not teach or suggest a one component Karl Fischer reagent comprising iodine and a base comprising imidazole and a substituted imidazole, wherein the molar ratio of imidazole to substituted imidazole is from about 0.3:2 to about 2:0.3, wherein the reagent is suitable for use as a one component reagent in volumetric Karl Fischer titrations, and wherein the reagent has a pH of from about 5.5 to about 8.

Based on the foregoing, dependent claims 34 and 35 are patentable over Scholz I in view of Scholz II, as applied to claims 1-9, 11-13 and 20-26 and 27-33, 36-39 and 42, and further in view of Sherman et al.

4. Rejection of Claim 41 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claim 41 under 35 U.S.C. §103(a) as being unpatentable over Scholz I in view of Scholz II in view of Fischer et al.

as applied to claims 14-19, 21 and 40 above, and further in view of Sherman et al. (Accreditation and Quality Assurance, May 1999).

Claim 41 depends directly from independent claim 40 and is patentable for the same reasons discussed above, as well as for the additional elements it requires. Notwithstanding the foregoing, Scholz I in view of Scholz II and further in view of Sherman et al. fail to teach or suggest each and every claimed element of the applicants' dependent claim 40.

The applicants' dependent claim 40 includes a pH range of from about 5.5 to about 8 as an additional element in a one component Karl Fischer reagent comprising iodine and from about 0.8 moles/Liter to about 1.3 moles/Liters imidazole, from about 0.6 moles/Liter to about 1 mole/Liter 2-methylimidazole, from about 0.1 moles/Liter to about 0.5 moles/Liter imidazole hydroiodide, from about 0.75 moles/Liter to about 1.6 moles/Liter sulfur dioxide, and from about 780 grams/Liter to about 820 grams/Liter diethylene glycol monoethylether and wherein the reagent is suitable for use as a one component reagent in volumetric Karl Fischer titrations.

As discussed above, Scholz I in view of Scholz II fails to teach or suggest each and every claimed element of the claims, nor is there any motivation in the references themselves, or available to one skilled in the art, to modify Scholz I in combination with Scholz II to arrive at the applicants' claim 1. As noted by the Office, Scholz I in view of Scholz II does not specifically indicate an optimal pH range for his Karl Fischer reagent. In an effort to remedy the admitted shortcomings of Scholz I in view of Scholz II, the Office cites for combination therewith, Sherman et al.

Sherman et al. discloses a Karl Fischer reagent comprising imidazole, sulfur dioxide, iodine, and potassium iodide in N-methylformamide. As the Office notes, a Google search indicates that Sherman et al. mentions in passing that the pH of the Karl Fischer reagent may be, *i.e.*, 5.5 to 8. Indeed, it is established in the art that this pH range is the optimal range, since in the pH range of 5.5 to 8 all of the sulfur dioxide is available as methyl sulfite; therefore the maximum reaction rate may be achieved.

However, even when combined, Scholz I in view of Scholz II and further in view of Sherman et al. fails to teach or suggest each and every claimed requirement of the

applicants' claims, as these references do not teach or suggest a one component Karl Fischer reagent comprising iodine and from about 0.8 moles/Liter to about 1.3 moles/Liters imidazole, from about 0.6 moles/Liter to about 1 mole/Liter 2-methylimidazole, from about 0.1 moles/Liter to about 0.5 moles/Liter imidazole hydroiodide, from about 0.75 moles/Liter to about 1.6 moles/Liter sulfur dioxide, and from about 780 grams/Liter to about 820 grams/Liter diethylene glycol monoethylether, wherein the reagent is suitable for use as a one component reagent in volumetric Karl Fischer titrations, and wherein the reagent has a pH of from about 5.5 to about 8.

Based on the foregoing, dependent claim 41 is patentable over Scholz I in view of Scholz II in view of Fischer et al. as applied to claims 14-19, 21 and 40, and further in view of Sherman et al.

CONCLUSION

In view of the above, applicants respectfully request favorable reconsideration and allowance of all pending claims.

Although applicants do not believe that any further fee is currently due, the Office is hereby authorized to charge any underpayment or to credit any overpayment of the above referenced fees to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully Submitted,



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